



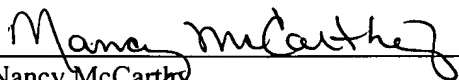
DOCKET NO: M0656.70046US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sasisekharan et al.
Serial No: 09/384,959
Confirmation No: 8533
Filed: August 27, 1999
For: RATIONALLY DESIGNED HEPARINASES DERIVED FROM
HEPARINASE I AND II
Examiner: Hutson, Richard G
Art Unit: 1652

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 14th day of June, 2004.


Nancy McCarthy

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:


Transmitted herewith is/are the following document(s):

- ☒ Information Disclosure Statement;
- ☒ PTO Form 1449 with cited references;
- ☒ Check in the amount of \$180.00; and
- ☒ Return Receipt Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check in the amount of \$180.00 is enclosed. If this amount is insufficient, the balance may be charged to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
Sasisekharan et al., *Applicant*

By: 
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Docket No. M0656.70046US00

Date: June 14, 2004

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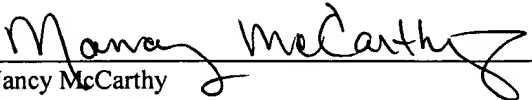
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Commissioner for Patents
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Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

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PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
M0656.70063US00	09/802,285	03/08/2001	Liu et al.
M0656.70069US00	09/951,138	09/12/2001	Sasisekhara et al.
M0656.70070US00	09/982,548	10/18/2001	Liu et al.
M0656.70076US00	10/108,195	03/27/2002	Kwan et al.
M0656.70086US00	10/291,337	11/08/2002	Liu et al.
M0656.70089US00	10/356,349	01/31/2003	Venkataraman et al.
M0656.70089US01	10/760,133	01/16/2004	Venkataraman et al.
M0656.70089US02	10/759,520	01/16/2004	Venkataraman et al.
M0656.70092US00	10/429,921	05/05/2003	Myette et al.
M0656.70094US00	10/441,970	05/20/2003	Sasisekhara et al.
M0656.70095US00	10/454,816	06/03/2003	Pojasek et al.
M0656.70096US00	10/753,761	01/07/2004	Sasisekhara et al.

The Applicant would like to bring to the Examiner's attention the enclosed search reports and communications from corresponding International Applications:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Mailing Date</u>	<u>Type of Report</u>
M0656.70046WO00	PCT/US99/19841	February 1, 2000	Invitation to Pay Additional Fees
M0656.70046WO00	PCT/US99/19841	April 27, 2000	International Search Report
M0656.70046WO00	PCT/US99/19841	June 21, 2000	Written Opinion

M0656.70046WO00	PCT/US99/19841	October 20, 2000	International Preliminary Examination Report
M0656.70063WO00	PCT/US01/07464	October 26, 2001	Invitation to Pay Additional Fees
M0656.70063WO00	PCT/US01/07464	January 22, 2002	International Search Report
M0656.70063WO00	PCT/US01/07464	February 27, 2002	Written Opinion
M0656.70063WO00	PCT/US01/07464	May 8, 2002	Written Opinion
M0656.70063WO00	PCT/US01/07464	August 5, 2002	International Preliminary Examination Report

The applicant would like to bring to the Examiner's attention the following other information:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Mailing Date</u>	<u>Type of Report</u>
M0656.70063US00	09/802,285	December 20, 2002	Office Communication
M0656.70063US00	09/802,285	October 3, 2003	Office Communication
M0656.70063US00	09/802,285	March 24, 2004	Office Communication

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.


By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

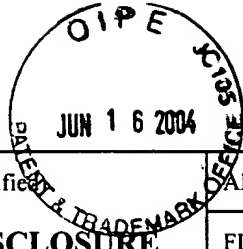
Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,
Sasisekharan et al., *Applicant*

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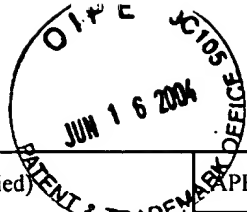
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FORM PTO-1449/A and B (Modified)				APPLICATION NO.: 09/384,959		ATTY. DOCKET NO.: M0656.70046US00	
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				APPLICANT: Sasisekharan et al.			
				GROUP ART UNIT: 1652		EXAMINER: Hutson, Richard G	
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U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A42	4,551,296		Kavesh et al.	11-05-1985
	A43	4,679,555		Sackner	07-14-1987
	A44	4,830,013		Maxwell	05-16-1989
	A45	4,928,694		Maxwell	05-29-1990
	A46	5,453,171		Ma et al.	09-26-1995
	A47	5,569,366		Chen et al.	10-29-1996
	A48	5,607,859		Biemann et al.	03-04-1997
	A49	5,687,090		Chen et al.	11-11-1997
	A50	5,752,019		Rigoutsos et al.	05-12-1998
	A51	5,759,767		Lakowicz et al.	06-02-1998
	A52	5,767,269		Hirsh et al.	06-16-1998
	A53	5,776,434		Purewal et al.	07-07-1998
	A54	5,855,913		Hanes et al.	01-05-1999
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	A56	5,874,064		Edwards et al.	02-23-1999
	A57	5,879,713		Roth et al.	03-09-1999
	A58	5,952,653		Covey et al.	09-14-1999
	A59	5,968,822		Pecker et al.	10-19-1999
	A60	5,985,309		Edwards et al.	11-16-1999
	A61	5,990,097		Kennedy	11-23-1999
	A62	5,993,846		Friedman et al.	11-30-1999
	A63	6,116,237		Schultz et al.	09-12-2000
	A64	6,136,295		Edwards et al.	10-24-2000
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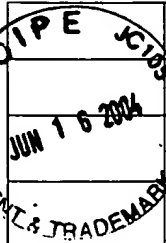
FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B12	EP	0 114 589	B1	President and Fellows of Harvard College	09-23-1987	
	B13	EP	0 140 781		DROPIC Societe Civile de Gestion de Droit de Propriete Industrielle CHOAY	05-08-1985	Y- ABSTRACT ONLY
	B14	EP	0 244 236	A2	Novo Industri A/S	11-04-1987	
	B15	EP	0 342 215	B1	Genentech, Inc.	08-25-1993	
	B16	EP	0 394 971	A1	President and Fellows of Harvard College	10-31-1990	
	B17	WO	92/01003	A1	Board of Regents, the University of Texas System	01-23-1992	
	B18	WO	93/05167	A1	Children's Medical Center Corporation	03-18-1993	
	B19	WO	93/10450	A1	Glyko, Inc.	05-27-1993	
	B20	WO	93/15406	A1	Imperial College of Science, Technology and Medecine	08-05-1993	
	B21	WO	93/19734	A1	Baker Norton Pharmaceuticals, Inc.	10-14-1993	
	B22	WO	94/12618	A1	Massachusetts Institute of Technology	06-09-1994	
	B23	WO	95/13830	A1	Massachusetts Institute of Technology	05-26-1995	
	B24	WO	96/01648	A1	Ibex Technologies R and D, Inc.	01-25-1996	
	B25	WO	96/32149	A1	Inhale Therapeutic Systems	10-17-1996	
	B26	WO	97/06783	A1	Baker Norton Pharmaceuticals, Inc.	02-27-1997	
	B27	WO	97/11684	A1	Ibex Technologies Inc.	04-03-1997	
	B28	WO	97/35562	A1	Danbiosyst UK Limited	10-02-1997	
	B29	WO	98/04902	A1	The State of Oregon	02-05-1998	
	B30	WO	98/31346	A1	Massachusetts Institute of Technology	07-23-1998	
	B31	WO	00/12726	A2	Massachusetts Institute of Technology	03-09-2000	
	B32	WO	00/65521	A2	Massachusetts Institute of Technology	11-02-2000	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	C39	AMEER et al., "A New Approach to Regional Heparinization: Design and Development of a Novel Immobilized Heparinase Device", <i>Blood Purification Meeting Information: The International Conference on Continuous Renal Replacement Therapies</i> , 16(2): 107-118, 1998. ABSTRACT ONLY		
	C40	BERRY et al., "Distinct Heparan Sulfate Glycosaminoglycans are Responsible for Mediating Fibroblast Growth Factor-2 Biological Activity Through Different Fibroblast Growth Factor Receptors", <i>The FASEB Journal Online</i> , Article #: 10.1096/fj.00-0661fj; 1-19, 2001.		
	C41	BIEMANN, "Four Decades of Structure Determination by Mass Spectrometry: From Alkaloids to Heparin", <i>J. Am. Soc. Mass. Spectrom.</i> , 13: 1254-1272, 2002.		
	C42	CARLSON et al., "Behavior of Antithrombin III Isoforms on Immobilized Heparins: Evidence that the Isoforms Bind to Different Numbers of Low-affinity Heparin Sites", <i>The Journal of Biological Chemistry</i> , 263(5): 2187-2194, 1988.		
	C43	CLAVIERIE et al., "Information Enhancement Methods for Large Scale Sequence Analysis", <i>Computers Chem.</i> , 17(2): 191-201, 1993.		

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	C44	CRUM et al., "A New Class of Steroids Inhibits Angiogenesis in the Presence of Heparin or a Heparin Fragment", <i>Science</i> , 230: 1375-1378, 1985.		
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	C46	EDWARDS et al., "Large Porous Particles for Pulmonary Drug Delivery", <i>Science Reprint Series</i> , 276: 1868-1871, 1997.		
	C47	EDWARDS et al., "Recent Advances in Pulmonary Drug Delivery Using Large, Porous Inhaled Particles", <i>J. Appl. Physiol.</i> , 85(2): 379-385, 1998.		
	C48	ERNST et al., "Expression in <i>Escherichia coli</i> , Purification and Characterization of Heparinase I from <i>Flavobacterium heparinum</i> ", <i>Biochem. J.</i> , 315: 589-597, 1996.		
	C49	ERNST et al., "Enzymatic Degradation of Glycosaminoglycans", <i>Critical Reviews in Biochemistry and Molecular Biology</i> , 30(5): 387-444, 1995.		
	C50	ERNST et al., "Direct Evidence for a Predominantly Exolytic Processive Mechanism for Depolymerization of Heparin-like Glycosaminoglycans by Heparinase I", <i>Proc. Natl. Acad. Sci. USA</i> , 95: 4182-4187, 1998.		
	C51	FOLKMAN et al., "Angiogenesis Inhibition and Tumor Regression Caused by Heparin or a Heparin Fragment in the Presence of Cortisone", <i>Science</i> , 221:719-725, 1983.		
	C52	GIOLDASSI et al., "Determination of Phosphorylated and Sulfated Linkage-region Oligosaccharides in Chondroitin / Dermatan and Heparan Sulfate Proteoglycans by High Performance Liquid Chromatography", <i>J. Liq. Chrom. & Rel. Technol.</i> , 22(13): 1997-2007, 1999.		
	C53	GODAVARTI et al., "Heparinase III from <i>Flavobacterium heparinum</i> : Cloning and Recombinant Expression in <i>Escherichia coli</i> ", <i>Biochemical and Biophysical Research Communications</i> , 225(3): 751-758, 1996.		
	C54	GODAVARTI et al., "A Comparative Analysis of the Primary Sequences and Characteristics of Heparinases I, II, and III from <i>Flavobacterium heparinum</i> ", <i>Biochemical and Biophysical Research Communications</i> , 229(3): 770-777, 1996.		
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	C57	HARENBERG et al., "Anticoagulant Effects and Tissue Factor Pathway Inhibitor after Intrapulmonary Low-Molecular-Weight Heparin", <i>Blood Coagulation and Fibrinolysis</i> , 7: 477-483, 1996.		
	C58	HAYES, "Prototeins", <i>American Scientist, the Magazine of Sigma Xi, the Scientific Research Society</i> , 86(3): 216-221, 1998.		
	C59	HORNER et al., "Heterogeneity of Rat Skin Heparin Chains with High Affinity for Antithrombin", <i>Biochem. J.</i> , 244: 693-698, 1987.		
	C60	JOHNSON et al., "Endothelial Cells Preparing to Die by Apoptosis Initiate a Program of Transcriptome and Glycome Regulation", <i>The FASEB Journal</i> , 18: 188-190, 2004.		
C61	KANABROCKI et al., "Heparin as a Therapy for Atherosclerosis: Preliminary Observations on the Intrapulmonary Administration of Low-Dose Heparin in the Morning Versus Evening Gauged by its Effect on Blood Variables", <i>Chronobiology International</i> , 8(3): 210-233, 1991.			
C62	KANABROCKI et al., "A Quest for the Relief of Atherosclerosis: Potential Role of Intrapulmonary Heparin - A Hypothesis", <i>Quarterly Journal of Medicine, New Series</i> , 83(300): 259-282, 1992.			
C63	KEISER et al., "Direct Isolation and Sequencing of Specific Protein-binding Glycosaminoglycans", <i>Nature Medicine</i> , 7(1): 123-128, 2001.			
C64	KISHIBE et al., "Structural Requirements of Heparan Sulfate for the Binding to the Tumor-derived Adhesion Factor/ Angiomodulin that Induces Cord-like Structures to ECV-304 Human Carcinoma Cells", <i>The Journal of Biological Chemistry</i> , 275(20): 15321-15329, 2000.			
C65	KREITZ et al., "Controlled Delivery of Therapeutics from Microporous Membranes. II. <i>In vitro</i> Degradation and Release of Heparin-loaded Poly (D,L-lactide-co-glycolide)", <i>Biomaterials</i> , 18(24): 1645-1651, 1997.			
C66	LECKBAND et al., "Characterization of the Active Site of Heparinase", <i>Abstracts of Papers Part I: Fourth Chemical Congress of North America</i> , 202(1): a56, 1991.			
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C68	LIU, Dongfang, et al., "Dynamic Regulation of Tumor Growth and Metastasis by Heparan Sulfate Glycosaminoglycans", <i>Seminars in Thrombosis and Hemostasis</i> , 28(1): 67-78, 2002.		
C69	LIU, Dongfang, et al., "Tumor Cell Surface Heparan Sulfate as Cryptic Promoters or Inhibitors of Tumor Growth and Metastasis", <i>PNAS</i> , 99(2): 568-573, 2002.		
C70	LIU, Jian, et al., "Strategy for the Sequence Analysis of Heparin", <i>Glycobiology</i> , 5(8): 765-774, 1995.		
C71	LIU, Jian, et al., "Characterization of a Heparan Sulfate Octasaccharide that Binds to Herpes Simplex Virus Type 1 Glycoprotein D", <i>The Journal of Biological Chemistry</i> , 277(36): 33456-33467, 2002.		
C72	LIU, Jian, et al., "Heparan Sulfate D-Glucosaminyl 3-O-Sulfotransferase -3A Sulfates N-Unsubstituted Glucosamine Residues", <i>The Journal of Biological Chemistry</i> , 274(53): 38155-38162, 1999.		
C73	MARCINIAK, "Differential Role of Fractionated Heparin in Antithrombin-III Proteolysis", <i>Blood</i> , 59(3): 576-581, 1982.		
C74	McLEAN et al., "Enzymic Removal of 2-O-Sulphato- $\Delta_{4,5}$ -Glycuronic Acid Residues from Heparin Oligosaccharides", <i>Proc. of the 7th Int'l. Symposium of Glycoconjugates</i> , p.68-69, 1983.		
C75	MURPHY et al., "Basic Fibroblast Growth Factor Binding and Processing by Human Glioma Cells", <i>Molecular and Cellular Endocrinology</i> , 114: 193-203, 1995.		
C76	MYETTE et al., "The Heparin / Heparan Sulfate 2-O-Sulfatase from <i>Flavobacterium heparinum</i> ", <i>The Journal of Biological Chemistry</i> , 278(14): 12157-12166, 2003.		
C77	MYETTE et al., "Molecular Cloning of the Heparin / Heparan Sulfate $\Delta_{4,5}$ Unsaturated Glycuronidase from <i>Flavobacterium heparinum</i> , its Recombinant Expression in <i>Escherichia coli</i> , and Biochemical Determination of its Unique Substrate Specificity", <i>Biochemistry</i> , 41(23): 7424-7434, 2002.		
C78	MYETTE et al., "Expression in <i>Escherichia coli</i> , Purification and Kinetic Characterization of Human Heparan Sulfate 3-O-Sulfotransferase-1", <i>Biochemical and Biophysical Research Communications</i> , 290(4): 1206-1213, 2002.		
C79	NATKE et al., "Heparinase Treatment of Bovine Smooth Muscle Cells Inhibits Fibroblast Growth Factor-2 Binding to Fibroblast Growth Factor Receptor but Not FGF-2 Mediated Cellular Proliferation", <i>Angiogenesis</i> , 3: 249-257, 1999.		
C80	NESHEIM et al., "Dependence of Antithrombin III and Thrombin Binding Stoichiometries and Catalytic Activity on the Molecular Weight of Affinity-purified Heparin", <i>The Journal of Biological Chemistry</i> , 261(7): 3214-3221, 1986.		
C81	PADERA et al., "FGF-2/ Fibroblast Growth Factor Receptor/ Heparin-like Glycosaminoglycan Interactions: A Compensation Model for FGF-2 Signaling", <i>The FASEB Journal</i> , 13(13): 1677-1687, 1999.		
C82	PIXLEY et al., "Preparation of Highly Stable Antithrombin-sepharose and Utilization for the Fractionation of Heparin", <i>Thrombosis Research</i> , 26(2): 129-133, 1982.		
C83	POJASEK et al., "Histidine 295 and Histidine 510 are Crucial for the Enzymatic Degradation of Heparan Sulfate by Heparinase III", <i>Biochemistry</i> , 39(14): 4012-1019, 2000.		
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EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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